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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,836	04/26/2005	Armin Breitenbach	12961/46601	8861

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EXAMINER	
VALENROD, YEVGENY	
ART UNIT	PAPER NUMBER
1621	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,836	BREITENBACH ET AL.	
	Examiner	Art Unit	
	YEVEGENY VALENROD	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-39 and 70-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-39 and 70-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following is a final office action in application # 10/532,836.

Rejection of claims 35-39 and 70-72 under 35 USC 112 2nd paragraph is withdrawn in view of applicants' amendments.

Rejection of claims 35-39 and 70-72 under 35 USC 102(b) over Meese et al. is maintained.

Rejection of claims 35-39 and 70-72 under 35 USC 103(a) over Meese et al is maintained.

Text of the rejections is repeated bellow and has been amended to accommodate the newly added claims73-79.

Reply to applicants' remarks and to the Declaration of Ralf Kanzler follows the repeated text of the rejections of record.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-39 and 70-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Meese et al (WO99/58478; already of record).

Meese et al disclose R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester (page 62, 3rd paragraph), (the compound of the instant claim 39). Meese discloses the compound as a free base and provides characterization of the compound in the form of: Rf value and HNMR data. The Rf value indicates that the compound was separated from the impurities on a TLC plate. The isolated compound therefore meets the limitations directed to % purity and salt content. The limitations directed to the therapeutically effective amount is inherently met by the disclosure of Meese et al. The term "therapeutically effective amount" has not been defined in the specification. It is unclear what therapeutic response is required for the amount to be therapeutically effective. Furthermore on pages where a dosing unit is described, specification teaches that the amount of active ingredient will vary based on weight and age of the patient. However the claim fails to specify who the patient is. A therapeutically effective amount for administration to a small mammal might well be far below the dosing units described in the specification.

Reply to applicants' remarks

Applicants' have traversed the anticipation rejection set forth above.

Applicants' have argued that the Rf value provided by Meese on page 62 is not the free base of fesoterodine. In the remarks applicants rely on Meese's disclosure on page 61 where a procedure for forming a hydrochloride salt is described. The said

disclosure is used to support the argument that what is disclosed by Meese on page 62, paragraph 3, is not the free base, but rather a hydrochloride salt.

Arguments presented in remarks have been carefully considered and have been found not persuasive to overcome the rejection of record.

1) Meese on page 62 Meese makes a clear distinction between the freebase and the hydrochloride of fesoterodine. In the preparation of the free base ester, Meese provides data for the Rf of the starting material and Rf of the product followed by the HNMR of the product. The reason Examiner is convinced that the data corresponds to the free base of fesoterodine and not to the hydrochloride is because right under the above described data Meese provides the NMR of the hydrochloride, which Meese also labels as “hydrochloride”. The two NMRs are carried out in the same deuterated solvent (deuterated chloroform) and display different peaks, which means the compound labeled as hydrochloride is not the same compound as the one labeled R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester. Regarding Meeses disclosure of preparation of the compound, it’s true, that procedure for how to prepare the hydrochloride (page 61, titled Salt formation) precedes the spectral data of the compounds prepared. However, on the previous page (page 60) a procedure for preparation of the freebase esters is provided. A reasonable interpretation of the data supplied for fesoterodine would be: 1) the ester (free base) was prepared and analyzed 2) the hydrochloride was prepared from the ester and analyzed. Therefore the Rf on page 63 is the Rf value of the free base of fesoterodine.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35-39 and 70-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meese et al (WO99/58478; already of record).

Scope of prior art

Meese et al disclose R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester (page 62, 3rd paragraph), (the compound of the instant claim 39). Meese discloses the compound as a free base and provides characterization of the compound in the form of: Rf value and HNMR data. The Rf value indicates that the compound was separated from the impurities on a TLC plate. The isolated compound therefore meets the limitations directed to % purity and salt content. Meese

et al. also teach that the compounds of their invention can be formulated into pharmaceutical preparations and pharmacological use of the inventive compounds (page 1, first 4 lines; page 35, lines 1-5).

Ascertaining the difference between prior art and instant claims

Meese is deficient in that they do not explicitly teach an amount of purified compound sufficient for a dosing unit.

Obviousness

One skilled in the art would have found it obvious to prepare enough of R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester to formulate it into a dosing unit. Since Meese et al teach preparation of pharmaceutical compositions, it would be obvious to prepare enough active ingredients for a pharmaceutical preparation. Preparing sufficient quantity with the instantly claimed purity is taught by Meese. The Rf value provided by Meese on page 62, corresponds to the compounds separation on thin layer chromatography, which provides one skilled in the art with means to isolate and purify the compound of the Meese on a larger scale. Such purification can via Prep scale TLC, both of which is a commonly utilized procedure that is well known to those skilled in the arts.

Regarding new claims 71 through 79. A specific amount of the free base of R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester as claimed by the applicant is obvious in view of the suggested disclosed dosing amounts for the drug Fesoterodine. Since Fesorerodine is a known pharmaceutical, one skilled in the art would know how much of the drug to formulate into a composition.

The amounts claimed by the applicant are therefore obvious unless unexpected results based on the specific amount of the drug are presented.

Reply to the remarks and to the Kanzer Declaration

In the remarks and in the Kanzer Declaration applicants have argued that conventional techniques, specifically chromatography, re-crystallization and distillation have failed to purify R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester. While examiner agrees that the above listed techniques might not be suitable for the purification of R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester, based on Meese's ability to separate the said compound via thin layer chromatography, one skilled in the art would be expect that a Prep-TLC technique would be successful in performing the purification. The expectation of success is based on the success of TLC demonstrated by Meese. Since TLC and Prep-TLC are based on the same principle of separation one would expect both to be successful in purification if one of the techniques has been shown to produce a pure product. The Rf value of Meese indicated that TLC is capable of purifying R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester. Based on that showing, one would have reasonable expectation of success in utilizing Prep-TLC for the same purpose.

Conclusion

Claims 35-39 and 70-79 are pending.

Claims 35-39 and 70-79 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

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